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Congress of the United States

House of Representatives

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March 8, 2016

Dr. Janet Woodcock
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

Thank you for appearing before the Subcommittee on Health on February 4, 2016, to testify at the hearing entitled "Examining Implementation of the Biologics Price Competition and Innovation Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on March 22, 2016. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Marsha Blackburn

1. Dr. Woodcock, the agency has posted online documents from the Zarxio review that suggest the agency and applicant agreed in November 2013 that the Zarxio labeling should be the same as its reference product labeling, even though the February 2012 draft guidance publicly stated the opposite. Is the agency departing privately from any other advice set forth publicly in its draft or final biosimilar guidance documents?

2. Dr. Woodcock, why did the agency reverse its decision that biosimilar labeling clearly identify a product as biosimilar and/or interchangeable? How does the agency justify this change with overwhelming multi-stakeholder support for transparent labeling and the agency's original position that transparent labeling was "necessary?"

3. Dr. Woodcock, at least seven biosimilar applications are pending at the FDA. Does FDA plan to continue taking approval actions on applications without disclosing its labeling policy to the public?

4. Dr. Woodcock, a number of stakeholders have called for more open public discussion of the complex scientific and policy issues surrounding interchangeability. What steps does FDA plan to take to address these calls for greater public discussion of the open questions on interchangeability? For example, does the agency plan to hold a public meeting, such as a Part 15 hearing, to receive input on these issues from all interested stakeholders?

5. Dr. Woodcock, GAO recently reported on deficiencies in the FDA's post-marketing safety (pharmacovigilance) program. Dr. What assurances do we have that the agency has the capability to quickly and effectively conduct better pharmacovigilance for highly immunogenic, complex medicines like biosimilars?

The Honorable John Shimkus

1. I have heard concerns from stakeholders following the first biosimilar approval regarding the information that was contained in the product label. My understanding is that a cut and paste label from the reference product was applied to the biosimilar that didn't even contain the simple statement that the product was approved as a biosimilar. This decision seems to be in stark contradiction to the original guidance that your agency released back in 2012, where you called for clear statements identifying the product as biosimilar and if it is interchangeable or not. Can you comment on when you will be releasing draft guidance in this important area and provide some insight as to the scientific rationale behind the change in policy from 2012 to when you approved the first biosimilar last Spring?

2. I want to reference two surveys, that I am going to submit to the record, conducted last year by the Alliance for Safe Biologic Medicines (ASBM). One is a physician survey (done before the Zarxio approval) and one is a pharmacist survey. In total, over 800 healthcare professionals from a variety of medical backgrounds were asked questions

regarding what they thought would be important to include on a biosimilar label. Without getting into specifics, it was overwhelmingly clear that physicians and pharmacists value transparency within product labeling so that they have a strong clinical understanding of the medicines they are prescribing. If our goal is to ensure the penetration of these products into the marketplace, shouldn't we enact a transparent labeling policy that creates confidence within the healthcare community?

3. In August 2015, FDA released draft guidance outlining their position on a naming structure for biological products. Appropriately, critical safety and pharmacovigilence considerations were addressed to ensure the safety of patients receiving these products. When describing your decision to include a four digit suffix following the core name of the biologic, there remained some outstanding questions that you presented back to stakeholders around interchangeability and whether there should be meaning associated with the suffix. I can understand on a cost basis why some people might want a random suffix, but I struggle to understand why the FDA, on scientific grounds, wouldn't want healthcare stakeholders to know or associate a meaningful suffix that points to a manufacturer or some other type of information. Can you comment on that? Also, with the recent WHO releasing their thoughts on naming, does the FDA feel the need to harmonize with them on a more global view on naming?

4. Last year, CMS finalized, as part of the Physician rule, a proposal that would combine biosimilars in the same class into a single code, thereby reimbursing them at an average rate. Physician stakeholders, when commenting on this proposed rule, overwhelmingly expressed concerns that this CMS policy could deter market entry and innovation by prioritizing price over all other features. Given that the goal of the biosimilars law was to create a pathway that facilitiates bringing these product to market, shouldn't we be fostering policies that drive down cost through competition? Did you do any studies or market analysis to assess the impact of this policy decision?

5. Congress was clear in writing the statute that the reimbursement methodology for reference products and biosimilars should remain independent, while providing an add-on payment designed to remove a clear financial incentive for providers. Can you confirm that the intent of CMS is to follow the statute and refrain from blending codes or reimbursement rates for the reference product with biosimilars or interchangeable biosimilars?

6. Under current law, a new biological product can be brought to market either by being approved as a new drug or by being licensed as a biological product.

    a. How, if at all, does a manufacturer's decision to use one pathway or the other affect (1) FDA's premarket review of the product, (2) the postmarket obligations of FDA and the manufacturer, and (3) the ability of another manufacturer to use that product as a reference product in a subsequent biosimilar application?

    b. Please identify each biological product currently on the market that has been approved as a new drug under 21 U.S.C. § 355(b). Has any of these products also been licensed as a biological product under 42 U.S.C. § 262(a)? If so, which one(s)?

c. Does FDA currently receive applications for new biological products under both pathways? How has the relative frequency with which the respective pathways are used changed over time? To the extent there have been changes, to what does FDA attribute them?

d. Please (1) identify any follow-on biological products that have been approved as generic drugs, and (2) explain how these products satisfied the statutory requirement that a generic drug be identical its reference product, given the complexity and variation inherent in the development of follow-on biological products.

7. In February 2012, FDA published a draft guidance document in which it stated that a biosimilar's labeling "should include all the information necessary for a health professional to make prescribing decisions," including a "clear statement" (1) advising that the product is a biosimiar, and (2) explaining whether the product has been approved as interchangeable with its reference product. But FDA subsequently approved a biosimilar without requiring either statement in its labeling, then deleted this requirement when it finalized the draft guidance in April 2015. Several months later, FDA stated in response to a question by members of this committee that health care professionals instead can find this information in the "Purple Book," FDA's published list of biological products.

   a. Does FDA continue to believe, as it stated in its 2012 draft guidance, that information about whether a product is a biosimilar, and whether patients may safely switch between the biosimilar product and its reference product, is "necessary for a health professional to make prescribing decisions"?

   b. Under the Food, Drug, and Cosmetic Act, a biological product must include "adequate directions for use" in its labeling. Does FDA consider the directions for a biosimilar product to be adequate if (1) they do not identify the product as a biosimilar, or (2) they do not describe whether a patient may safely switch between the biosimilar product and its reference product? Why or why not?

   c. Does the FDA consider the Purple Book to be a part of a biological product's labeling?

   d. Are health care professionals required to consult the Purple Book when making prescribing decisions? What information has FDA reviewed regarding when, and to what extent, health care professionals actually consult the Purple Book?

8. In April 2015, FDA indicated in a guidance document that it may allow a biosimilar to be marketed to treat diseases and conditions for which it has not been studied, if the reference product has been approved for those indications and the biosimilar's safety and potency for those indications can be inferred—or "extrapolated"—from studies for other indications.

   a. If a product is approved for both studied indications and extrapolated indications, does FDA intend to differentiate between the two types of indications in the product's label? If not, how does it intend to communicate these differences to patients and health care providers?

b. What postmarket surveillance will FDA require for extrapolated indications? How, if at all, will the requirements vary by circumstance?

c. Under what circumstances would FDA rescind approval for an extrapolated indication? What procedural requirements and evidentiary standards would apply?

9. Please identify the requirements for manufacturing practices and inspections that apply to manufacturers of biological products, including biosimilars.

d. Does the nature or frequency of establishment inspections differ between small molecule drugs and biological products? If so, how?

e. Is the manufacturer of a biological product subject to requirements that differ from those applicable to the manufacturer of a small molecule drug?

f. If a biological product is approved as a new drug rather than licensed as a biological product, does it affect which requirements apply?

g. Are any biological products currently being imported from India or China? Given recent concerns regarding the quality of finished drugs and ingredients manufactured in those countries, and the complexity of biological products relative to small molecule drugs, what is FDA doing to ensure the safety of any biological products imported from those countries?

10. Please describe what steps FDA has taken, and plans to take in the future, to educate patients and health care professionals about the risks and benefits of biosimilars. What has it spent on such education efforts to date, and what funding is necessary for future education efforts? How will FDA's education efforts balance the need to promote health care savings through increased use of lower-cost products against the need to ensure that patients and health care professionals understand any relevant risks?

11. Under current law, several important responsibilities for regulating drugs (including biological drugs) are assigned to the U.S. Pharmacopeial Convention (USP), a nonprofit organization that publishes an official compendium of drugs. For example, a drug must meet the standard of identity described in the USP compendium, and generally must print the scientific name selected by USP—called an "established name"—on its label.

a. How, if at all, do USP's responsibilities and activities differ between biological products and small molecule drugs? Does FDA believe that USP's current role with respect to biological products is appropriate?

b. Despite USP's statutory role in the naming of biological drugs, FDA's recent draft guidance on naming does not discuss USP. Has USP been consulted in the development of FDA's policy on naming conventions? To what extent does USP agree with the current thinking proposed in the draft guidance? To the extent USP disagrees, what are the practical implications of any disagreement?

c. FDA's draft guidance on naming describes how to select a biological product's "proper name," which is the statutory term for a biological product's scientific name. But a biological drug's scientific name also is regulated as an "established name" under the drug statutes, and the draft is silent about how the guidance would apply to these "established name" requirements. Would a "proper name"

under this guidance always be the product's "established name," or are there circumstances in which a product's "proper name" and "established name" might be different?

12. Dr. Woodcock, does the FDA believe that it would be in the best interest of the Biosimilar pathway if the BPCIA's patent dispute provisions were interpreted as mandatory, as opposed to an optional dispute procedure that a biosimilar may choose to follow?

13. Is it possible that FDA might approve an interchangeable product without first issuing guidance on interchangeability?

14. Is there anything Congress can do to help FDA speed up issuing the guidance?

15. We hear a lot of concern about consistency, or lack of consistency, across review divisions. This seems especially important regarding the willingness and ability of reviewers in different divisions to embrace the use of 21st century drug development tools – such as biomarkers and patient-reported outcomes, innovative clinical trial designs, and new statistical approaches. What are you doing to try to ensure that application sponsors can reliably get consistent advice and approaches when they bring new and creative drug development ideas to FDA, regardless of the review division with which they are working?

16. The complexity and uniqueness of each biologic medicine require that FDA ensure that all biologics and biosimilars are thoroughly tested and meet the highest patient safety and manufacturing quality standards. Given the complex manufacturing process when even slight changes can cause major problems, what resources does FDA have designated to inspect biosimilar manufacturing facilities? Are FDA inspectors receiving additional, specialized training to inspect these facilities? Are there any specific differences in FDA protocol for the inspection of a biosimilar manufacturer versus a reference biologic manufacturer? A recent report in the Economic Times indicated that Indian maker of the Ramuzab an injectable biosimilar for macular degeneration produced and approved for use in India had curtailed distribution after a number of adverse events associated drug had been reported. In addition, media reports that some manufacturers in India that have had serious quality control problems identified in their manufacturing of much simpler generic drugs are planning to produce biosimilars. How many FDA inspectors are there in India who have expertise in reviewing biologics and/or biosimilars manufacturing facilities? Is this this adequate to assure patient safety?

17. I understand that FDA still has not provided details on the specifics of interchangeable products; but can you tell me broadly in your mind what an interchangeable looks like?

18. Can the agency comment on whether the concept of finger-print like similarity at the analytical level is linked to interchangeability requirements?

19. The agency has mentioned plans to issue interchangeability guidance before the end of the year. Is this still on track and can you talk to some of the challenges around what seems to be a very scientifically complex determination.

20. FDA has yet to release guidance on what evidence companies will be required to present to the Agency to prove they have met the requirements to receive an interchangeable

designation for biosimilars. At the same time, companies are making significant advancements in how to analyze biologics with increasing precision, potentially reducing the necessity for expensive clinical trials. As the agency develops that guidance, will you leave room for future advancements in analytical technologies so that these products can be brought to market faster without unnecessary trials?

21. Does FDA believe that biosimilars have the potential to be different enough from the reference product to require a different label?

22. As you know, many have serious concerns regarding the naming of biosimilars to provide transparency and ensure patient safety. Given recent efforts by the FDA to protect patient safety by issuing import alerts and the blacklisting of some manufacturers, has the FDA considered any labeling requirements to disclose the manufacturer and country of the origin of biosimilars?

23. I appreciate the agencies focus on assimilating the purple book, but some have suggested that physicians and pharmacists will continue to utilize the product labeling as they have been accustomed to do. Do you think that the purple book is sufficient for providing the necessary safety information to providers? What is the harm in providing more information to providers about the characteristics of the product in the label?

24. In 2012, FDA issued a Draft Guidance[1] stating that the labeling of a proposed biosimilar product should clearly state that the product is approved as a biosimilar for a given indication, and whether the product has been determined to be interchangeable. In the Final Guidance issued in April, the Agency removed these statements. Can you please comment on why the Agency removed these statements from the Final Guidance? Does the Agency disagree with physicians that believe these two pieces of information to be material to prescribers?

25. The complexity and uniqueness of each biologic medicine require that FDA ensure that all biologics and biosimilars are thoroughly tested and meet the highest safety standards. If a child is to be given a biosimilar drug for pediatric arthritis, or pediatric inflammatory bowel disease, shouldn't their parent have the peace of mind of knowing that that biosimilar has undergone clinical testing for those specific conditions?

26. FDA recently released its proposed guidance on the non-proprietary naming of biosimilars. In it you specifically noted that you were not addressing future interchangeable biosimilars at this time, and asked for feedback on how to approach those products. Just a few months earlier in July, however, CMS proposed reimbursement policies for biosimilars entering the market without making such a distinction about interchangeable biosimilars. Is FDA communicating with CMS on where the regulatory pathway is on interchangeables? Do you think CMS should be addressing reimbursement for interchangeable products before your agency has developed the approval pathway?

27. In addition to the regulatory approval requirements necessary for manufacturers to invest in the development of biosimilars, the other major variable is government reimbursement for biosimilars. In its recently proposed rule on biosimilars reimbursement, CMS left a number of questions unanswered, questions which are closely linked to the progress FDA

[1] Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf)

is making on a number of its guidances. Is FDA communicating with CMS on these issues?

28. Under Section 7002(e)(2) of the Biological Price and Innovation Competition Act, biological products that have been approved under an NDA under Section 505 of the Federal Food, Drug, and Cosmetic Act will be transitioned into a BLA under Section 351 of the Public Health Service Act by March 23, 2020. How does the FDA plan to address implementation of these transition provisions?

29. What is the FDA's stance on using post marketing data from countries like India for approval of biosimilars in the US?

30. The BPCIA includes a series of disclosure and patent exchange provisions that are often referred to collectively as the "patent dance." The goal of the patent dance is to compel the branded company and biosimilar applicant to identify only those patents that are relevant for purposes of litigation. However, in July, the Court of Appeals for the Federal Circuit ruled that the patent dance is optional.

FDA's Orange Book, which covers small molecule drugs, includes a listing of all relevant patents, while the Purple Book, which covers biologics, does not.

31. Does the FDA have the authority, on its own accord, to require that sponsors list all of the patents covering their biological products in the Purple Book?

32. I understand that FDA does not involve itself in disputes involving pharmaceutical patents; however, is there any reason why FDA would oppose the mere listing of patents in the Purple Book?

33. Is the FDA concerned about the threat of improperly listed patents? As part of Medicare Modernization Act of 2003, Congress gave generic applicants the ability to challenge the listing of a patent in the Orange Book by filing a counterclaim against the branded company in response to an infringement suit. [FFDCA §505(c)(3)(D) (ii)(I)]. Would FDA have any issues with Congress implementing a similar approach with respect to the Purple Book?

The Honorable Michael C. Burgess

1. In accordance with the transition requirements of the BPCIA, certain biological products that were originally approved under Section 505 of the FDC Act, like insulin and human growth hormone, will be deemed approved under Section 351 of the PHS Act. There are a number of unanswered questions with respect to what it means to be a product that is deemed licensed under the PHS Act, such as those related to exclusivity (including pediatric exclusivity), non-proprietary naming, A ratings and interchangeability, and scientific standards. Does FDA intend to address these questions in its forthcoming guidance document and how likely is it that the Agency will release such a guidance this year?

2. For the first biosimilar approved, FDA did not require the label to identify the product as a biosimilar or to delineate the indications for which clinical data was generated. This decision seems to contradict FDA's past statements and guidance on this issue. What was the agency's rationale for omitting this important information?

3. The first biosimilar label did not include any information about the different types of studies the company conducted or clinical data that was submitted. This type of scientific information is extremely important. Could the sponsor proactively provide this information to doctors and payers or would such activity be considered off-label promotion? Why or why not?

4. Healthcare providers have indicated that they want to know, when prescribing biosimilars, which indications were studied clinically and which were not. How do you plan to make sure providers have adequate information to feel comfortable prescribing biosimilars?

5. If FDA adopts the distinguishable non-proprietary names for biologics unique to the license holder, what will happen when companies acquire or divest products?

6. In 2010 and 2012, the agency characterized interchangeability as a stringent standard, and as a higher standard than biosimilarity. However, more recently, FDA has used different language calling interchangeability simply an "additional" showing. What led to this change in FDA's position?

7. It is critical that FDA have clear review standards and processes in place to protect patient safety and ensure efficacy of biosimilar medicines prior to making decisions about these applications. It is also vital that the process used to develop these standards is transparent so that patients and the public have a full and fair opportunity to review and comment upon these standards before they are finally adopted. On a regular and ongoing basis, what specifically will FDA do to obtain input from patients, providers, and industry experts in biosimilar policy discussions? Will upcoming guidance on labeling, interchangeability, and other key issues come in draft form so these groups have an opportunity to review and comment on them before they become final?

8. At the Senate HELP Committee hearing on biosimilars on September 17, 2015, Dr. Woodcock stated that FDA has a multi-year plan to educate patients about biosimilars. Was this developed in consultation with patient groups? Will FDA commit to working with patient groups to review this plan and make any necessary modifications?

9. Factors, such as cost or state pharmacy laws, may force patients to switch from a biologic medicine to a biosimilar. How is FDA factoring this in to patient safety standards when approving biosimilars, labeling, and interchangeability?

The Honorable Gus Bilirakis

1. Dr. Woodcock, FDA will be transitioning a number of biologics that were previously approved as drugs into the biologics regulatory regime by 2020. How does the agency plan on doing so as seamlessly as possible?

The Honorable Renee Ellmers

1. During the February 4, 2015 Energy and Commerce Health Subcommittee hearing titled, "Examining Implementation of the Biologics Price Competition and Innovation Act" I stated to you that a letter to Acting Commissioner Ostroff from the House Doctor's Caucus dated December 21, 2015 had not received a response. I requested that it be submitted for the hearing record. If you could please provide the committee and the members who signed that letter a status on the response to it, I would greatly appreciate it. Again, this is a very important issue that has been raised to the House Doctors Caucus attention by physicians and patients.

2. You stated at the Senate hearing last year that provider and patient confidence in biosimilars is critical to the success of the program and that the agency needs to ensure that the scientific framework is "bulletproof." Recently, twelve members of the House Doctor's Caucus – including myself – sent a letter to Acting Commissioner Ostroff with concerns regarding a lack of transparency on the label for the first biosimilar approved last year as well as the FDA's suggestion that physicians reference the Purple Book regarding interchangability of biosimilars. Mr. Chairman, I respectfully ask that this letter be entered into the record. Dr. Woodcock, I along with the other members of the Doctor's Caucus who signed this letter would appreciate a timely response. In the interim could you speak about the FDA's actions prior to and during the consideration of the approval of the first biosimilar product to ensure physician confidence in these products?

3. This first approved biosimilar was given a four digit suffix abbreviating the company's name in order to differentiate it from the reference product. The draft guidance, while requesting additional feedback on the matter, proposes a different approach that would assign a random suffix that is "devoid of meaning." Can you walk me through FDA's current thinking on this and the factors you are going to consider before making your final decision?

4. The FDA has done an admirable job in uncovering problems with Indian manufacturing of generic medicines. However, numerous examples still exist of Indian companies with dubious production records continuing to sell products in the US. Given that biosmiliars are far harder to produce than small molecule generics, what extra safeguards, such as demanding spotless export records for three years, will FDA put in place if Indian biosimilars are ever approved for sale in US?"

The Honorable Susan Brooks

1. Dr. Woodcock, if a biosimilar is not initially determined to be interchangeable at the time of approval, could it eventually achieve such status and, if so, can you explain the

logistical and communications challenges such a situation would present and how FDA would deal with them?

2. The patent provisions contained within BPCIA were carefully crafted after much debate among all stakeholders. They create a two-round scheme for resolution of potential patent disputes. The first opportunity for patent litigation is designed to provide resolution of at least some relevant patents far in advance of a biosimilar approval. Are you concerned that even though you may have approved a product, it may still not reach patients because of pending patent litigation that must be resolved?

    a. If not, why are you not concerned given that the goal is to get these new medicines to patients?

    b. If yes, is there anything that Congress should do to help provide a more certain process to ensure patent disputes are resolved in a timely manner?

The Honorable Chris Collins

FDA has stated a need to identify biological products *clearly*, in order to differentiate among biological products that have not been determined to be interchangeable. The only approved biosimilar received a nonproprietary name followed by a 4-letter code signifying the company responsible for marketing the medication. However, we have heard from constituents that are biologics prescribers that a suffix must also be memorable.

1. Will the FDA's next approval of a biosimilar provide clear guidance on biosimilar naming? Can you share any insight on how FDA may proceed with regard to the four-letter suffix and differentiating products?

Physicians want the most accurate information possible so that they can make decisions in the best interest of their patients, undoubtedly. Physicians are responsible for prescribing the biosimilar and treating adverse side effects that may result.

2. How does the agency plan to increase transparency in a biosimilar's prescribing information, whereby the prescription drug labeling information will clearly indicate whether the information is based on the biosimilar product or on the reference biologic?

3. What is your agency doing to ensure safety of a biosimilar drug for more than one indication? Will clinical testing be required for each indication before it can be used to treat patients for that indication? For example, if a reference biological medication is approved for five different indications, it has been specifically tested in different patient groups with each of the five different medical conditions. Will this be the same for biosimilars?

4. Europe has preceded the U.S. in approvals of biosimilars. Will FDA use data from those approvals, and specifically post-market data, to inform FDA's decisions on indication approvals?

The Honorable Frank Pallone

Biosimilars are an exciting new frontier in American medicine. Because this is a new, emerging marketplace, we need to make sure we do everything possible to incentivize manufacturers to enter the market. For this to happen, it is important that the Administration has a clear and coherent position on biosimilars.

1. Please describe the extent to which CMS has collaborated with FDA on implementing biosimilars policy?

2. Did CMS seek FDA guidance when drafting its Part B reimbursement policy?

When CMS published the final rule on Part B payments, the agency noted that many commenters were concerned that the proposed payment approach may make it more difficult to track safety monitoring of codes because individual biologic products could not be distinguished on claims. Historically, post-approval drug safety surveillance has been a difficult endeavor. I'm concerned that due to differences between biosimilars and regular generics, that safety tracking *may be even more difficult* for biosimilars.

3. Prior to release of the Rule, did CMS consult with FDA about the potential effects of the proposed approach on their ability to track drug safety?

4. Please discuss CMS' efforts to address this issue.

One of the most difficult decisions to make in payment policy for prescription drugs is the balance between patient access and spurring innovation. Not unexpectedly, CMS indicated in the Part B Payment Final Rule that the agency received considerable comment on this topic.

Several stakeholders have indicated that they are concerned that grouping biosimilar products for payment purposes would discourage innovation.

1. Can you comment on how the agency addressed these concerns in the final payment rule?

FDA has been very explicit that biosimilars are not the same as generics. However, CMS has indicated that because of the degree of similarity of biosimilars to their reference products, that the agency believes it is appropriate to price biosimilars in a similar manner to generics.

2. Can you discuss this apparent difference in opinions?

The FDA has taken the approach of having two differing levels of biologic drugs: Biosimilars and interchangeable biologics.

3. Although there are currently no interchangeables at this time, has CMS considered developing a future payment structure that reflects these differences?

The Honorable Lois Capps

Dr. Woodcock, we have already heard that one main area that needs to be clarified in order to set up a robust biosimilars market is to gain clarity on how these products should be labeled. As a nurse, I understand the importance of an accurate and useful labeling system for health care providers. But it is also an important tool for patients, so that they understand what they are taking and can be active participants in their own care. Clearly, all the stakeholders in this conversation are eager for clear guidance from FDA on how these life-saving products should be labeled.

1. Dr. Woodcock, can you tell us more about the steps FDA plans to take to ensure that these labels are useful and usable for not only providers and payers, but for patients as well? How is their experience factoring into FDA's thinking on this matter?

Dr. Woodcock, as you noted in your testimony, confidence from patients and health care professionals is critical to the success of the biosimilar market. I believe this confidence in part will come through a better understanding of biosimilars by patients and health care professionals. You have indicated that FDA will take a multi-phase approach to education and outreach, including message development, training programs, and partnerships with outside organizations.

2. I appreciate that FDA is taking a multi-pronged approach to education and outreach efforts. Can you please discuss further the multi-phase education and outreach plan FDA has developed, as well as what resources FDA has, or may need, to fully implement this plan? As you know, the fifth authorization of PDUFA and the House passed Cures has emphasized the benefit for including the patient perspective in the drug development process. How will FDA incorporate the patient perspective as a part of your planning and outreach efforts related to biosimilars?